

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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| <b>UNITED STATES OF AMERICA,</b> | ) | Criminal No.: 09-CR-10035-DPW |
|                                  | ) |                               |
| <b>v.</b>                        | ) |                               |
|                                  | ) |                               |
| <b>SHANE DOYLE,</b>              | ) |                               |
|                                  | ) |                               |
| <b>Defendant.</b>                | ) |                               |
|                                  | ) |                               |

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**GOVERNMENT'S RESPONSE TO ORDER TO SHOW CAUSE**

The government hereby responds to the Court's April 17, 2012 Order to Show Cause as to why the Court should not vacate the defendant's guilty plea and proceed to trial on the merits of the charges against Mr. Doyle. That Order also asks the government for a "full and detailed explanation of the principled basis on which it chose mid-trial to abandon a felony prosecution of the employer." The government herein also responds to that aspect of the Court's Order.

**I.      The Court Should Not Vacate the Plea.**

As set forth in the government's supplemental sentencing memorandum [Docket #41], the Court should not vacate Shane Doyle's guilty plea because he admitted that he committed the felony misbranding violation with which he was charged, and because his plea agreement with the government represented a fair exercise of the government's discretion in not charging Mr. Doyle with other felony conduct relating to his falsification of Institutional Review Board ("IRB") approvals. That falsification conduct formed the basis of a civil settlement agreement that was incorporated by reference and attached to Mr. Doyle's plea agreement, and which is only effective if the Court accepts the plea agreement. Vacating the plea agreement, in addition

to exposing Mr. Doyle to a trial on the merits on the misbranding charge, also exposes him to being charged with the IRB conduct. The government does not seek that outcome. Nor, the government believes, does Mr. Doyle. Although the government does not purport to speak for the defendant, it understands that, while he has asked the government to revisit his plea agreement in light of his former employer Stryker Biotech, LLC's ("Stryker") guilty plea in United States v. Stryker Biotech, LLC, et al., Criminal No. 09-CR-10330-GAO, he does not wish this Court, on its own, to vacate his guilty plea. Because the government has declined to revisit his plea agreement, this Court's vacatur of his guilty plea would leave Mr. Doyle facing not only the prospect of trial on the existing charges, but perhaps the leveling of new felony charges against which he would be forced to defend.

The parties have reached an agreement to resolve the entirety of Mr. Doyle's conduct with a plea to a single Food Drug & Cosmetic Act felony, in violation of 21 U.S.C. §§331(a), 333(a)(2), with a joint recommendation of a sentence of 1 year of probation, and a civil agreement to disgorge commissions earned based on false IRB approvals. Neither party is pressing for a trial on these issues, in part, the government believes, because the plea agreement was and is fair, and is superior to the Court's suggested alternative of vacating the plea.

Among the reasons not to vacate the plea is that Mr. Doyle committed the crime charged, as he admitted and as found by this Court at the Rule 11 Hearing in April 2009. In addition, the parties have both performed under that plea agreement – Mr. Doyle cooperated with the government and the government has made a motion for a downward departure from the Sentencing Guidelines pursuant to USSG §5K1.1. Mr. Doyle has also paid the government the

\$75,000 called for by the civil settlement agreement. Neither Mr. Doyle nor the government is moving to vacate the plea.

To vacate Mr. Doyle's guilty plea to the felony on the ground that Mr. Doyle's plea is unfair, in light of Stryker's guilty plea to a misdemeanor count, "debases the judicial proceeding at which a defendant pleads and the court accepts his plea."<sup>1</sup> United States v. Hyde, 520 U.S. 670, 676 (1997). Mr. Doyle has already been sworn in open court and stated that he actually committed the crime charged, and after he acknowledged that he pled guilty because he is guilty, the Court found a factual basis for the plea and explicitly announced that it accepted the plea. The guilty plea was a "grave and solemn act" which was "accepted only with care and discernment." Id. at 677 (internal citations and quotations omitted). Allowing a defendant to wait to see if other defendants obtain better terms or are not charged or are acquitted, and then re-analyzing a defendant's already-entered guilty plea, turns the "otherwise serious act of pleading guilty into something akin to a move in a game of chess." Id. In a broader sense, it would turn plea and cooperation agreements with a host of people, such as bank robbery getaway drivers, drug mules or street dealers, penny stock boiler room peddlers and beyond, into a long-term game of chance in which the government's decision not to bring charges against

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<sup>1</sup>The Court also suggested in the sentencing hearing on March 19, 2012 that the fair thing to do would be to allow Mr. Doyle to withdraw his guilty plea and replace it with a guilty plea to a misdemeanor. [Transcript of March 19, 2012 Hearing at 10]. First, Mr. Doyle has not sought to withdraw his guilty plea. Second, it is within the discretion of the Executive Branch whether to charge Mr. Doyle with a misdemeanor or a felony. United States v. Batchelder, 442 U.S. 114, 123-124 (1979)(“This Court has long recognized that when an act violates more than one criminal statute, the Government may prosecute under either so long as it does not discriminate against any class of defendants.”).

others; a jury's acquittals of other defendants; or other defendants' guilty pleas to lesser or reduced charges would allow a Court to revisit arm's-length agreements that are supported by the solemn process of a Rule 11 hearing. In fact, even when a defendant does move to withdraw a plea – which the defendant here has not done – his dissatisfaction with the deal he made, including dissatisfaction resulting from the acquittal of co-defendants on the same charges to which the defendant pleaded guilty, is not a basis to set aside a plea. See Moreno-Espada v. United States, 666 F.3d 60, 67 (1st Cir. 2012) (stating that "it is well settled that post-sentencing 'buyer's remorse' is not a valid basis on which to dissolve a plea agreement") (citations omitted); United States v. Torres-Rosa, 209 F.3d 4, 9 (1st Cir. 2000) ("[A] defendant's 'second thoughts about ... the wisdom of his earlier decision' do not themselves comprise a plausible basis for allowing him to withdraw an earlier guilty plea.") (citation omitted); United States v. Martinez-Molina, 64 F.3d 719, 733 (1st Cir. 1995) (affirming district court's refusal to grant defendant's motion to withdraw his guilty plea where the court found that the defendant's claim of coercion "merely reflected second thoughts about the wisdom of his decision after learning that two codefendants had been acquitted at trial").

Moreover, it does not appear that Fed. R. Crim. P. 11 permits the Court to vacate a guilty plea in the circumstances presented here. A court may refuse to accept a guilty plea if it finds that the defendant does not understand certain rights, the plea is involuntary or there is no factual basis for it. Fed.R.Crim. P. 11(b)(1), (2) and (3). The only part of Rule 11 that addresses the vacatur of a guilty plea following the court's acceptance of the plea is Rule 11(d), which provides that a defendant may withdraw a guilty plea after the court accepts it but before sentence is

imposed, if “(A) the court rejects a plea agreement under Rule 11(c)(5); or (B) the defendant can show a fair and just reason for requesting the withdrawal.” In United States v. Cruz, 709 F.2d 111, 115 (1<sup>st</sup> Cir. 1983), the U.S. Court of Appeals for the First Circuit found that a district court exceeded its authority under Rule 11 by rejecting a guilty plea -- subsequent to having accepted it -- because the sentences received by co-defendants were significantly higher than that which Cruz was facing on the misdemeanor charge to which he and the government had agreed. The Cruz court held that once a court accepts a guilty plea with a factual basis it has no authority to change its mind on the basis of information in a presentence report, at least where there is no evidence of fraud. Id.<sup>2</sup> See also United States v. Ventura-Cruel, 356 F.3d 55, 61 (1<sup>st</sup> Cir. 2003)(affirming district’s court rejection of guilty plea because it met “exception” to general rule that court “generally may not accept a guilty plea and then subsequently reject it” because court learned afterwards that there may not be a factual basis to support the plea). It is easy to see how a defendant might be disadvantaged if the court were permitted to vacate a bargained-for guilty plea based on unfavorable information about the defendant gleaned during later co-defendant litigation. The law must protect each side equally.

Citing the Supreme Court’s recent decision about the contours of the Sixth Amendment right to effective counsel during the plea negotiation process, Missouri v. Frye, 132 S. Ct. 1399

<sup>2</sup>The First Circuit in United States v. Kirkculer, 918 F.2d 295, 301 n.9 (1<sup>st</sup> Cir. 1990) noted that Cruz has been “disapproved” by it to the extent it relied on double jeopardy analysis and is inconsistent with Ohio v. Johnson, 467 U.S. 493 (1984). See United States v. Ritsema, 89 F.3d 392, 399 n.6 (7<sup>th</sup> Cir. 1996) (Despite apparent overruling on double jeopardy analysis found in Johnson, “[w]e nevertheless cite Cruz, as have many other courts, for the proposition that Rule 11 does not authorize the court to withdraw its prior acceptance of a plea agreement.”).

(2012), this Court noted in its order to show cause the importance of plea bargaining to the criminal justice system. See id. at 1407 (“To note the prevalence of plea bargaining is not to criticize it.”). Pointing to the great benefits to all parties of plea bargaining, the Supreme Court held that in “order that these benefits can be realized, however, criminal defendants require effective counsel during plea negotiations.” Id. at 1407-1408. Here, there is no suggestion from anyone that Mr. Doyle has not received effective counsel from the plea negotiations through the current stages of this case. In fact, as noted in the government’s previous submission on this issue, Mr. Doyle’s counsel effectively negotiated such that potentially more serious charges were the subject of a civil settlement agreement, rather than a criminal charge.<sup>3</sup>

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<sup>3</sup>Citing Santobello v. New York, 404 U.S. 257 (1971), this Court noted that there is no federal right to have a judge accept a plea bargain. While that is true, and is somewhat codified in Fed. R. Crim. P. 11, most of the cases on this point involve the prosecution’s breach of a promise in connection with the plea agreement, or an insufficient factual basis for the plea. Neither of those situations exists here. Nor is this a case of the government trying to take sentencing out of the Court’s hands by entering into a plea agreement purely driven by sentencing considerations. E.g., United States v. Escobar Noble, 653 F.2d 34 (1<sup>st</sup> Cir. 1981). The First Circuit, in Ventura-Cruel, 356 F.3d at 59, offered some context on the interplay between Santobello and Rule 11:

It is well settled that a defendant does not have an absolute right to plead guilty. Santobello v. New York, 404 U.S. 257, 262, 92 S.Ct. 495, 30 L.Ed.2d 427 (1971). The Supreme Court has stressed that the plea “phase of the process of criminal justice, and the adjudicative element inherent in accepting a plea of guilty, must be attended by safeguards to insure the defendant what is reasonably due in the circumstances.” Id. Rule 11 provides a defendant with these essential safeguards.

See also Ritsema, 89 F.3d at 399 (“the principle that a plea agreement once accepted is binding is signaled by Rule 11 itself.”); United States v. Skidmore, 998 F.2d 372, 375 (6<sup>th</sup> Cir. 1993) (“the district court is not authorized to go beyond the confines of Rule 11 in accepting or rejecting plea agreements.”)(internal citations and quotations omitted). As in Cruz, the Skidmore court also noted that courts may “bypass the limits of Rule 11 only in cases involving the commission of a

The government has previously (April 17, 2012) responded to the Court's questions about its views of the root fairness of holding Mr. Doyle to a felony plea when his employer, Stryker, pled guilty to a misdemeanor. The traditional bases for withdrawing guilty pleas, such as claims of actual innocence or claims that the plea was somehow not voluntary, are not present here. "When a proper Rule 11 colloquy has taken place, a guilty plea enjoys a presumption of verity and the 'fair and just' Rule 11((d)(2)(B) escape hatch is narrow." United States v. Mays, 593 F.3d 603, 607 (7<sup>th</sup> Cir.); cert. denied, 130 S.Ct. 3340 (2010). Accord, United States v. Catanese, 2009 WL 3230908 (D. Mass.)(Stearns, J.). For all of these reasons, the government urges the Court not to vacate Mr. Doyle's plea.

## **II. The Government's Plea Agreement With Stryker Biotech Was an Appropriate Exercise of Its Discretion.**

The Court has also ordered the government to explain why it chose, mid-trial, to resolve the then-pending felony charges against Stryker with a guilty plea to a misdemeanor.

By way of background, on October 11, 2011, the grand jury returned a Superseding Indictment, charging, inter alia, defendants Stryker, Mark Philip, William Heppner, Jeffrey Whitaker, and David Ard, in connection with a conspiracy to defraud the United States and the Food and Drug Administration ("FDA") by impeding, impairing, obstructing and defeating through craft, trickery, deceit and dishonest means the lawful function of the FDA to protect the health and safety of the public by ensuring that medical devices marketed and distributed in the United States (i.e., OP-1 and Calstrux) were safe and effective for their intended uses. [Docket

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fraud upon the court." Id. at 375 n.1.

#145 in United States v. Stryker Biotech, LLC, et al., Criminal No. 09-CR-10330-GAO (“Stryker”). Count 1 charged all of the defendants with conspiring to defraud the United States and the FDA and to commit wire fraud, all in violation of 18 U.S.C. §371; Counts 2 through 6 charged the defendants with wire fraud, in violation of 18 U.S.C. §1343; Counts 7 through 12 charged Stryker with misbranding a medical device in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. §331(k); and Count 13 charged Stryker with making false statements in its annual report to the FDA, in violation of 18 U.S.C. §1001.

On January 9, 2012, the first day of trial, the district court severed defendant Mark Philip, the President of Stryker, based on its determination that there was an irreconcilable conflict between defendant Stryker, which had asserted its attorney-client privilege on certain matters, and Philip, who asserted the right to use some of that material in his own defense. [Stryker Tr. 1:4-5]. Philip’s motion to sever had been made for the first time in the case the Friday before trial began, January 6, 2012. [Stryker Docket #264]. The district court’s decision to sever Philip was just the beginning of a series of evidentiary rulings that fractured and undermined the government’s case in unexpected ways.

That same day, January 9, 2012, the district court (O’Toole, D.J.) also severed Count 13, which charged Stryker with making false statements in its annual report to the FDA, on the ground that it was “unfair” to the individual defendants remaining in the case (all of whom were sales managers), “where there’s no evidentiary connection to them to the false statement” alleged in Count 13, which false statement and associated conduct were also alleged as overt acts of the conspiracy in Count 1. [Stryker Tr. 1:28]. As late as the final pre-trial conference, held on

January 4, 2012, the district court had denied the defendants' motions to sever that count. The court left open whether Count 13 would have to be severed again, with respect to Philip and Stryker, because of the privilege issue. [Stryker Tr. 1:28].

Following this severance of the false statement count, the defendants also sought to exclude evidence of the false statement from the conspiracy or wire fraud charges. The defendants had complained that the indictment did not identify any person who acted in furtherance of the conspiracy by making the false statement, and that to the extent that there was any defendant as to whom the statement was reasonably foreseeable, that person was Philip, who had been severed. [Stryker Tr. 1:9-14]. The government noted that the conspiracy alleged the filing with the FDA as an overt act, and that the evidence would show that senior executives at Stryker knew what was going on and that the "collective knowledge" instruction from United States v. Bank of New England, N.A., 821 F.2d 844 (1<sup>st</sup> Cir. 1987) would be appropriate. [Stryker Tr. 1:15-16, 18-19]. However, the district court questioned whether there was sufficient evidence to find it an overt act: that is, whether members of the alleged conspiracy anticipated that this kind of false statement would have been made in the same way they would have reasonably expected that emails would be sent (under a wire fraud theory). [Stryker Tr. 1:20-21].

On January 12-13, 2012, the parties gave opening arguments. The government argued, among other things, that by promoting the OP-1/Calstrux combination in the face of knowledge that the combination was not FDA approved or clinically tested, and had been associated with reports of not working well together or even adverse events, Stryker intended to defraud the FDA and surgeons, and had actually misled some surgeons. [Stryker Tr. 4:27, 54]. Stryker

argued that this was a misguided prosecution because, among other reasons, the OP-1/Calstrux combination helped patients, and surgeons were not tricked into using it, pressing that the government had not interviewed certain surgeons identified in the superseding indictment (as recipients of OP-1/Calstrux mixing instructions), but that the defense had and would offer their testimony that they had not been deceived or defrauded. [Stryker Tr. 4:76-77]. Stryker further contended that the government's investigation began when Stryker self-reported to the FDA some misconduct by its own employees, which suggested that it was not trying to defeat the lawful functions of the FDA. [Stryker Tr. 4:98-99].

On January 13, 2012, the government put on its first witness, Stryker's former Vice-President of Sales. His testimony resulted in a number of objections and sidebar conferences regarding various evidentiary issues, including the breadth of the co-conspirator exception to the hearsay rule. The district court's rulings on some of these issues – such as finding inadmissible certain conversations between the witness and another Stryker home-office (as opposed to sales) employee – meant that the government was unable to adduce some of the evidence it had intended to present. [Stryker Tr. 5:109].

On January 17, 2012, the government and Stryker signed a plea agreement pursuant to Fed. R. Crim. P. 11(c)(1)(C). [Stryker Docket #290]. The plea agreement arose from a call Stryker made to the government on the Friday night of the first week of trial. [Stryker Tr. 6:28]. The government said that it thus "responded to things as they happened." [Stryker Tr. 6:28].

The plea agreement provided that Stryker would plead guilty to a one-count superseding information that charged misdemeanor misbranding of a medical device in violation of 21 U.S.C.

331(k), 333(a)(1), and 352(f)(1), a lesser included offense of the felony misbranding charges that were included in the superseding indictment, and the government would dismiss Counts 1 through 13 of the superseding indictment against Stryker. [Stryker Docket #290; see Stryker Docket #295]. The parties agreed that the appropriate disposition was a fine of \$15 million, which included \$12.5 million in “gross gain resulting from the offense, and relevant conduct from other instances of misbranding between February 2006 and February 2008.” [Stryker Docket #290 at 2-3]. Stryker also agreed to provide the government with all documents and records in its possession, custody or control relating to the criminal proceedings in the District of Massachusetts concerning OP-1 and Calstrux which were not covered by the attorney-client privilege or work product doctrine, unless such privileges were waived. [Stryker Docket #290 at 6].

At the plea hearing, the government stated that the agreement was in the public interest because Stryker was agreeing to pay what the government believed was a sufficient fine, taking into account all the factors and sentencing guidelines. [Stryker Tr. 6:15]. The total \$12.5 million represented just a portion of the total sales of Calstrux and OP-1 that were used together, because the government recognized that some surgeons would have mixed the two on their own, without the sales force’s influence. [Stryker Tr. 6:16]. Judge O’Toole accepted the plea agreement and found the amount of the fine “reasonable enough as a necessary and appropriate penalty,” particularly given that a “precise calculation [was] not likely and that there’s a penalty for the misbranding alleged.” [Stryker Tr. 6:19].

For strategic reasons, animated in part by its desire to focus on and strengthen the case

against the remaining two defendants, and based on the events that played out during the first week of trial, as well as the fact that after indictment but before the start of trial, Stryker had sold the OP-1 medical devices at issue (having previously taken the other medical device at issue, Calstrux, off the market) and had terminated the employment of the individuals involved in selling and marketing these devices, the government took up Stryker's offer to plead to misdemeanor misbranding.<sup>4</sup> Judge O'Toole, who presided over the Stryker case, and was aware of the issues facing the lawyers, determined that he should accept that plea.

This Court has questioned the government's strategic decision to enter into the plea agreement with Stryker. But Judge O'Toole accepted the company's plea, and in later denying the defendants' renewed motion to dismiss the defraud prong of the conspiracy charge given that guilty plea – finding it better resolved at the Rule 29 stage – Judge O'Toole noted “substantial doubt whether the government’s evidence will suffice to clear that [Rule 29] hurdle,” particularly with respect to whether the defendants had the requisite mental state to have specifically intended the defraud object of the conspiracy. [Stryker Tr. 7:3-7, 14-16]. Regardless of the possibility that differences of opinion may exist over the merits of the government's decision, the government made that decision based on its best analysis of the evidence that remained against

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<sup>4</sup>Although the Court asked for a "full and detailed" explanation of why the government agreed to plead Stryker to a misdemeanor, the government assumes that the Court was not requesting the substance of internal deliberations within the U.S. Attorney's Office, which are protected by a number of privileges, including work product and deliberative process. See Department of Interior v. Klamath-Water Users Protective Ass'n, 532 U.S. 1, 8 (2001); Northrop Corp. v. McDonnell Douglas Corporation, 751 F.2d 395, 399 n.2 (D.C. Cir. 1984)(“courts have proceeded on the basis that the government has a special set of privileges - e.g., executive privilege, state secrets, deliberative process - which it may invoke to prevent disclosures that would be inimical to national security or its internal deliberations.”).

the two defendants in the trial, following the district court's severance and evidentiary rulings, as well as the government's theory of the case, the district court's view of the evidence, and the government's burden of proving its case beyond a reasonable doubt. See United States v. Thurston, 456 F.3d 211, 216 (1st Cir. 2006) ("In order to gain a conviction without risking an unsuccessful trial, prosecutors frequently discount the sentence they offer in a plea bargain by the probability of loss."), cert. granted and judgment vacated on other grounds, 552 U.S. 1092 (2008).

While government decisions are appropriately subject to public debate, further excursion into the government's exercise of its prosecutorial discretion in this matter implicates separation of powers concerns. The government has broad discretion as to whom to prosecute and on what charges, e.g., Wayte v United States, 470 U.S. 598, 607 (1985) (upholding government's selective prosecution of only those draft dodgers who reported themselves), and thus, "a district court is limited in its ability to second-guess the government's decisions on whether and what to prosecute." United States v. Garcia Valenzuela, 232 F.3d 1003, 1006-07 (9<sup>th</sup> Cir. 2000); see United States v. Thompson, 621 F.2d 1147, 1151 (1<sup>st</sup> Cir. 1980) (defendant complained that government offered nolo contendere pleas to other corporate defendants but not to it and argued that he therefore had a right to nolo plea or to ask the court to "scrutinize the prosecution's decision," however, the "prosecution's decision concerning plea recommendations is to be made according to the dictates of its own discretion and we need not inquire into its reasoning."). "Few subjects are less adapted to judicial review than the exercise by the Executive of his discretion in deciding when and whether to institute criminal proceedings, or what precise charge

shall be made, or whether to dismiss a proceeding once brought.” Newman v. United States, 382 F.2d 479, 480 (D.C. Cir. 1967)(affirming U.S. Attorney’s decision to allow one co-defendant to plead to lesser included misdemeanor, but not the other). Thus, separation of powers concerns generally prohibit courts from reviewing charging decisions absent a *prima facie* showing that they rested on an impermissible basis, such as gender, race or denial of a constitutional right. United States v. Armstrong, 517 U.S. 456, 464 (1996); Wayte, 470 U.S. at 607-608. There is no such claim here.

The government took care in exercising its discretion to enter into a plea agreement with Stryker as well as with Mr. Doyle, and given the absence of any issue of constitutional dimension in its decisions, the government respectfully submits that there is no basis to further delve into its decision-making, or to set aside the plea.

**III. Conclusion**

The government respectfully requests that the Court end its inquiry into Mr. Doyle's guilty plea and set the matter for sentencing.

Respectfully submitted,

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